

REMARKS

Claims 1-48 remain pending in the application.

Claims 1-8, 10-33 and 36-48 over Burns

In the Office Action, claims 1-8, 10-33 and 36-48 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Burns et al. U.S. Patent No. 6,379,929 ("Burns"). The Applicant respectfully traverses the rejection.

Claims 1-8 and 10-17 recite, *inter alia*, a volume of deformable material in a pathway which, in use, changes its state so as to cause a change of the rate of fluid flow along the pathway. Claim 18 recites, *inter alia*, a volume of deformable material situated in a pathway which, in use, changes its state so as to cause a change of a rate of fluid flow along the pathway and a hydrophobic portion which defines a path along which the deformable material is guided. Claims 19-24 recite, *inter alia*, a volume of deformable material situated in a recess which, in use, changes its state so as to cause a change of a rate of fluid flow along a pathway and a hydrophobic portion which defines a path along which the deformable material is guided. Claims 25 and 36 recite, *inter alia*, a deformable material disposed within a pathway whereby, in use, a change of state of the deformable material causes a change of a rate of fluid flow along the pathway. Claims 26-33 recites, *inter alia*, a volume of deformable material disposed adjacent a pathway whereby, in use, a change of state of the deformable material causes a change of a rate of fluid flow along the pathway. Claim 37 recites, *inter alia*, a volume of deformable material disposed within a pathway which, in use, changes its state so as to cause a change of a rate of fluid flow along the pathway and a hydrophobic region which defines a path along which the deformable material is guided. Claim 38 recites, *inter alia*, a volume of deformable material disposed adjacent a pathway which, in use, changes its state so as to cause a change of a rate of fluid flow along the pathway and a hydrophobic region which defines a path along which the deformable material is guided. Claims 39 and 44 recite, *inter alia*, a recess adjacent a pathway, a plug of deformable material in the pathway so that the material substantially restricts

flow of fluid in the pathway, and changing a state of the deformable material so that at least a portion of the material passes into the recess permitting flow of the fluid along the pathway. Claim 40 recites, *inter alia*, a recess substantially adjacent a pathway, a volume of deformable material in a recess, and changing a state of the deformable material so that a portion of the material passes into the pathway thereby substantially restricting flow of a fluid along the pathway. Claims 41 and 43 recite, *inter alia*, locating a volume of deformable material in a pathway so that it substantially restricts flow of fluid along the pathway, and changing a state of the deformable material so that a portion of the material passes along a predetermined path thereby permitting flow of the fluid along the pathway. Claim 42 recites, *inter alia*, locating a volume of deformable material in a pathway so that it substantially permits the flow of fluid along the pathway, and changing a state of the deformable material so that a portion of the material passes along a predetermined path thereby substantially restricting flow of the fluid along the pathway. Claim 45 recites, *inter alia*, a recess located substantially adjacent a pathway, a plug of deformable material in the pathway so that the material substantially restricts fluid flow in the pathway, and changing a state of the deformable material so that a portion of the material passes along a predetermined path into the recess thereby permitting flow of the fluid along the pathway, wherein the predetermined path is defined by hydrophobic regions. Claim 46 recites, *inter alia*, providing a recess located substantially adjacent a pathway, locating a volume of deformable material in the recess, and changing a state of the deformable material so that a portion of the material passes along a predetermined path into the pathway thereby substantially restricting flow of fluid along the pathway, wherein the predetermined path is defined by one or more hydrophobic regions. Claim 47 recites, *inter alia*, locating a volume of deformable material in a pathway so that it substantially restricts fluid flow along the pathway, and changing a state of the deformable material so that a portion of the material passes along a predetermined path thereby permitting flow of the fluid along the pathway, wherein the predetermined path is defined by one or more hydrophobic regions. Claim 48 recites, *inter alia*, locating a deformable material in a first pathway, flowing a fluid along the first pathway past the

material, and changing the state of the material so that a portion of the material passes along a second pathway so as to restrict fluid flow along the first pathway, the second pathway being defined by one or more hydrophobic regions.

Burns appears to teach an isothermal amplification of nucleic acids, such as DNA and RNA, in a microfabricated structure. By necessity such amplification reactions occur at temperatures that fluctuate only to a very tiny degree and are therefore distinguished from, *inter alia*, the polymerase chain reaction. The microfabricated structure for maintaining such a constant temperature environment comprises silicon, glass or quartz components including channels and reaction chambers.

The Examiner appears to have overlooked at least three distinctions between the transport that occurs in the microfabricated channels and that which occurs in the pathways defined in the claims.

i) The channels of Burns are defined as "microdroplet transport channels" (column 5, line 14f). Although "channel" takes a conventional technical meaning, the fluids within them are not in a state of continuous flow. "Microdroplets" are discrete, restricted volumes of fluid which can be manipulated in more than one direction within the channels. For example, Burns at column 8, lines 35 to 49 refers to a bubble pump moving "an effective quantity of fluidic samples along the channel", this quantity later being qualified as a drop. Column 33, beginning at line 34 defines further examples of how to direct such microdroplets along the channels.

By very precisely controlling the movement of droplets within the microfabricated structure, Burns teaches that microdroplets of nucleic acids can be merged with microdroplets of enzymes under conditions of temperature and pressure required for amplification reactions to occur (column 34, beginning at line 66). This produced a "merged microdroplet", the movement of which can also be controlled.

The term "flow" in the claims of this application cannot be compared to such droplet movement. The present invention is intended as a flexible and

cheap mechanism for controlling the type of continuous fluid flow that would conventionally be controlled by taps and valves along the length of the pathway.

ii) There is no disclosure in Burns of a volume or plug of deformable material that is separate, discrete and unconnected to the walls of the capillaries or channels as required by the present claims.

iii) It is acknowledged that Burns does disclose regions within the microfabricated channels that have different hydrophilicity. Hydrophobic surfaces may be deposited and patterned on, e.g., the silicon, glass or quartz substrates from which the channels are made.

As described in Burns, beginning at column 33, line 57, these patterned, hydrophobic regions contribute to the separation of nanolitre drops of fluid from microdroplets present within the channels. Also, these drops are moved along hydrophobic regions using pressure differentials or thermal/electrical potentials to provide a control for the positioning of the drops within the channels

In the present invention, it is not the fluid drops that move along the hydrophobic regions of the pathways but the deformable material. Its movement along such patterned regions varies the effective channel size, restricting or promoting fluid flow.

Burns fails to teach the claimed inventions of claims 1-8, 10-33 and 36-48.

Accordingly, for at least all the above reasons, claims 1-8, 10-33 and 36-48 are patentable over the prior art of record. It is therefore respectfully requested that the rejection be withdrawn.

Claims 9, 34 and 35 over Burns in view of Jones

In the Office Action, claims 9, 34 and 35 were rejected under 35 U.S.C. §103(a) as allegedly being obvious over Burns in view of Jones U.S. Patent No. 5,267,585 ("Jones"). The Applicant respectfully traverses the rejection.

Claims 9, 34 and 35 are dependent on claims 1 and 25 respectively, and are allowable for at least the same reasons as claims 1 and 25.

Claim 9 recites, *inter alia*, a volume of deformable material in a pathway which, in use, changes its state so as to cause a change of the rate of fluid flow along the pathway. Claims 34 and 35 recite, *inter alia*, a deformable material disposed within a pathway whereby, in use, a change of state of the deformable material causes a change of a rate of fluid flow along the pathway.

As discussed above, Burns fails to teach a deformable material in a pathway, which, in use, a change of state of the deformable material causes a change of rate of fluid flow along a pathway, as claimed by claims 9, 34 and 35.

The Office Action relies on Jones to allegedly make up for the deficiencies in Burns to arrive at the claimed invention. The Applicant respectfully disagrees.

Jones appears to teach a method and device for controlling fluid flow along a pathway that is provided between an inlet and outlet by a channel within a regulating chamber. An elastomeric element is provided within the channel that is deformable, the extent of this deformation controlling the rate of liquid flow in the channel.

The interrelationship between this elastomeric element, the regulating chamber and the channel is distinct from those claimed embodiments of the present invention that utilize a recess, pathway and a deformable volume or plug to control fluid flow. Jones' deformation of the elastomeric element causes it to expand so as to completely conform to the chamber and fill across the channel. By contrast, such an arrangement, i.e., the positioning of the volume or plug completely within the recess and across the pathway is not encompassed within the present claims.

With respect to the other claimed embodiments of this invention, this Jones fails to disclose any embodiment wherein the elastomeric material moves along a predetermined path.

It is implied throughout Jones that the deformation of the elastomeric element is achieved using physical force. For example, the text refers to the means of deformation having to be "released". Although the use of physical force to deform volumes is within the scope of the present invention, it is one of a plurality of deformation mechanisms that can include, *inter alia*, heat,

pressure and radiation. Jones lacks flexibility in the uses to which it can be put when compared to the inventions claimed in the present invention.

Neither Burns nor Jones, either alone or in combination, disclose, teach or suggest a deformable material in a pathway, which, in use, a change of state of the deformable material causes a change of rate of fluid flow along a pathway, as claimed by claims 9, 34 and 35.

Accordingly, for at least all the above reasons, claims 9, 34 and 35 are patentable over the prior art of record. It is therefore respectfully requested that the rejection be withdrawn.

Claim 9 over Gubinski in view of Jones

In the Office Action, claim 9 was rejected under 35 U.S.C. §103(a) as allegedly being obvious over Gubinski et al. U.S. Patent No. 5,278,079 ("Gubinski") in view of Jones. The Applicant respectfully traverses the rejection.

Claim 9 is dependent on claim 1, and is allowable for at least the same reasons as claim 1.

Claim 9 recites, *inter alia*, a volume of deformable material in a pathway which, in use, changes its state so as to cause a change of the rate of fluid flow along the pathway.

Gubinski appears to teach a method and apparatus for sealing a device such that fluid can no longer pass through it. A polymer that expands on contact with water is positioned in a portion of a tube that has a smaller diameter than that of the majority of the tube. When water is introduced into the tube, the polymer increases in volume to completely fill the lower diameter section, thus preventing water from exiting.

Gubinski relates specifically to the field of medical diagnostics where small volumes of liquid such as blood and saliva are involved. It is of paramount importance that the polymer expands quickly and completely to seal the device being used and prevent even fractional loss of liquid.

A number of distinctions therefore exist between this prior art invention and that claimed in the present application.

i) The expandable polymer never occupies an "intermediate" position where the fluid can pass through the device by flowing over the expandable material, unlike the deformable volumes of this application.

The expandable polymer is not (even partially) retained in a recess in the tube, nor can the expansion of the polymer be described as a movement "along a predetermined path".

iii) Once the initial expansion of the polymer has occurred to provide the requisite seal it is difficult to reverse this situation whereby to unseal or open the tube. This contrasts with the present invention wherein the deformability and determined movement of the plug or volume of material lends itself to re-usability, a significant practical advantage.

As discussed above, Jones fails to teach a volume of deformable material in a pathway which, in use, changes its state so as to cause a change of the rate of fluid flow along the pathway, as claimed by claim 9.

Neither Gubinski nor Jones, either alone or in combination, disclose, teach or suggest a volume of deformable material in a pathway which, in use, changes its state so as to cause a change of the rate of fluid flow along the pathway, as claimed by claim 9.

Accordingly, for at least all the above reasons, claim 9 is patentable over the prior art of record. It is therefore respectfully requested that the rejection be withdrawn.

Claim 35 over Gubinski

In the Office Action, claim 35 was rejected under 35 U.S.C. §103(a) as allegedly being obvious over Gubinski. The Applicant respectfully traverses the rejection.

Claim 35 is dependent on claim 25, and is allowable for at least the same reasons as claim 25.

Claim 35 recites, *inter alia*, a deformable material disposed within a pathway whereby, in use, a change of state of the deformable material causes a change of a rate of fluid flow along the pathway.

As discussed above, Gubinski fails to disclose, teach or suggest a deformable material disposed within a pathway whereby, in use, a change of state of the deformable material causes a change of a rate of fluid flow along the pathway, as claimed by claim 35.

Accordingly, for at least all the above reasons, claim 35 is patentable over the prior art of record. It is therefore respectfully requested that the rejection be withdrawn.

Conclusion

All objections and rejections having been addressed, it is respectfully submitted that the subject application is in condition for allowance and a Notice to that effect is earnestly solicited.

Respectfully submitted,



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